Complete Summary

GUIDELINE TITLE

Adult preventive health care: immunizations.

BIBLIOGRAPHIC SOURCE(S)

University of Michigan Health System. Adult preventive health care: immunizations. Ann Arbor (MI): University of Michigan Health System; 2005 Nov. 11 p. [2 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: University of Michigan Health System. Adult preventive health care: immunizations. Ann Arbor (MI): University of Michigan Health System; 2004 May. 9 p.

* * REGULATORY ALERT * *

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

On October 3, 2005, The U.S. Food and Drug Administration (FDA) and CDC notified consumers and health care providers of five reports of Guillain Barre Syndrome following administration of Meningococcal Conjugate Vaccine A, C, Y, and W135 (trade name Menactra), manufactured by Sanofi Pasteur. It is not known yet whether these cases were caused by the vaccine or are coincidental. FDA and CDC are sharing this information with the public now and actively investigating the situation because of its potentially serious nature. Guillain Barre Syndrome (GBS) is a serious neurological disorder that can occur, often in healthy individuals, either spontaneously or after certain infections. GBS typically causes increasing weakness in the legs and arms that can be severe and require hospitalization. Because of the potentially serious nature of this matter, FDA and CDC are asking any persons with knowledge of any possible cases of GBS occurring after Menactra to report them to the Vaccine Adverse Event Reporting System (VAERS) to help the agencies further evaluate the matter. See the FDA Web site for more information.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Influenza
- Pneumonia
- Tetanus
- Diphtheria
- Hepatitis A
- Hepatitis B
- Measles
- Mumps
- Rubella
- Varicella
- Meningitis

GUIDELINE CATEGORY

Prevention

CLINICAL SPECIALTY

Allergy and Immunology
Family Practice
Geriatrics
Infectious Diseases
Internal Medicine
Preventive Medicine

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To implement an evidenced-based strategy for routine adult immunizations

TARGET POPULATION

Adults, 18 years and older

INTERVENTIONS AND PRACTICES CONSIDERED

Adult immunizations, including:

1. Influenza vaccine
2. Pneumococcal polysaccharide vaccine
3. Tetanus (and diphtheria) booster
4. Hepatitis B vaccine series (Twinrix for combined hepatitis A & B vaccination
5. Hepatitis A vaccine series (Twinrix for combined hepatitis A & B vaccination)
6. Measles, mumps, rubella (MMR) vaccine
7. Varicella vaccine series
8. Meningococcal vaccine
    - Menactra® for adults <55 years of age
    - Meningococcal polysaccharide (Menomune) for adults >55 years of age

MAJOR OUTCOMES CONSIDERED

- Disease attributable mortality and morbidity
- Disease progression
- Adverse effects
- Hospitalization for complications

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

2005 Version

The literature search for this update began with the results of the literature search performed for the previous version of this guideline (2004). The update search included all subsequent Advisory Committee on Immunization Practice (ACIP) statements through May 2005. The search focused on statements addressing vaccines for: influenza, pneumococcal pneumonia, tetanus, hepatitis B, hepatitis A, measles, mumps, rubella, varicella, and meningococcal disease.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of evidence reflect the best available literature in support of an intervention or test:

A. Randomized controlled trials
B. Controlled trials, no randomization
C. Observational trials
D. Opinion of expert panel

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Conclusions were based on prospective randomized clinical trials if available, to the exclusion of other data; if randomized controlled trials were not available, observational studies were admitted to consideration. If no such data were available for a given link in the problem formulation, expert opinion was used to estimate effect size.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Consideration of benefits, harms, costs, and patient preferences.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

University of Michigan Health System (UMHS) guidelines are reviewed by faculty members of departments to which the content is most relevant. This guideline concerning adult immunizations was reviewed by members of the departments of: Family Medicine and Internal Medicine's Divisions of General Medicine and of Infectious Diseases. Guidelines are approved by the Executive Committee for Clinical Affairs.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC): The following key points summarize the content of the guideline. Refer to the original guideline document for additional information.

The levels of evidence [A-D] are defined at the end of the "Major Recommendations" field.

Influenza Vaccines

Initial dose: Inactivated (injectable)

- Adults >50 years old [B]
- Persons with chronic illnesses (e.g., cardiovascular, pulmonary, renal, metabolic, sickle cell disease, immunosuppression/human immunodeficiency virus [HIV])
- Residents of long-term care facilities [B]
- Women who are pregnant
- Health care workers, including home care and long-term care workers [A]
- Household contacts and out-of-house caregivers of children <6 months
- Others who can transmit influenza to a high risk population

Initial dose: Live attenuated (intranasal)

- For non-pregnant healthy persons <50 years old in priority populations, live attenuated vaccine may be used as an alternative to inactivated vaccine.

  (Non-priority healthy persons <50 years old may receive either vaccine if supply allows.)

Revaccinate annually

- Persons eligible under criteria for initial immunization

Pneumococcal Polysaccharide Vaccine

Initial dose:

- All adults >65 years old [B]
- Residents of nursing home and long-term care facilities
- Persons with chronic illness (e.g., cardiovascular, pulmonary [except asthma], diabetes, kidney or liver disease, alcoholism, cerebrospinal fluid leak, cochlear implants, sickle cell disease, asplenia and other immunosuppressive conditions, chemotherapy, steroid use)
- Native Americans and Native Alaskans

Revaccinate once ≥5 years after initial dose only for the following high risk patients

- Age: persons age ≥65 if initial vaccine was given ≥5 years previously at age <65 [A].
- Chronic disease: highest risk for pneumococcal infection or rapid decline in antibody (e.g., asplenic, sickle cell disease, transplant recipient, HIV, nephrotic syndrome, chronic renal failure, immunosuppressed).

Tetanus (and Diphtheria) Booster (Td)* (primary series assumed)**

Revaccinate every 10 years

- All patients [A]. A single booster at age 50 years may be equivalent to the decennial booster if primary series and teenage booster was completed [C].

Revaccinate in ≥5 years

- Patients with wounds (other than clean or minor wounds)

*A newly licensed tetanus-diphtheria-acellular pertussis vaccine is available for adults. The Advisory Committee of Immunization Practices (ACIP) recommendations for its use will be published.

**If primary series not given: 3 doses Td at 0, 4 weeks, and 6 to 12 months.

Hepatitis B Vaccine Series (Note: For combined hepatitis A and B vaccination, use Twinrix)

Three doses at 0, 1, and 6 months

- Adults in high-risk groups including patients receiving plasma derivatives/clotting factor concentrates repeatedly, individuals with multiple sex partners, men who have sex with men, hemodialysis patients (early in disease), intravenous (IV) drug users and sexual partners, immigrants from and travelers to high risk areas, persons with recent sexually transmitted diseases (STDs)
- Healthcare workers/public safety workers/students who are exposed to blood
- Clients and staff of institutions for the developmentally disabled and correctional facilities
- Household contacts and sexual partners of persons with chronic hepatitis B virus (HBV) infection

No repeat dose needed (No information on long-term efficacy. Some patients may need booster doses in future.)

Hepatitis A Vaccine Series (Note: For combined hepatitis A and B vaccination, use Twinrix, three doses at 0, 1, and 6 months)

Two doses at 0 and 6 to 12 months

- Persons with chronic liver disease [A], persons with clotting factor disorders
- Men who have sex with men, illicit drug-users
- Travelers to countries where there is higher or intermediate hepatitis A virus (HAV) endemicity
- Persons with occupational risk who work with HAV-infected primates or HAV in a research lab

Measles, Mumps, Rubella Vaccine (use MMR vaccine) Note: In women of childbearing age, avoid pregnancy for at least 4 weeks after immunization

Two doses at 0 and ≥1 month

- No evidence of immunity* to measles and are:
    - Health care workers
    - College students (first dose may be required before admission to classes)
    - Travelers to foreign countries
    - Asymptomatic HIV+ patients without severe immunosuppression (CD4 >200)
    - Recently exposed to measles or are in an outbreak setting

One dose

- Women of childbearing age with no evidence of immunity* to rubella [A] (Avoid pregnancy for at least 4 weeks after immunization.)
- Health care workers with evidence of immunity* to measles but no evidence of immunity* to rubella
- Evidence of immunity* to measles but no evidence of immunity* either to rubella or to mumps and are:
    - College students (first dose may be required before admission to classes)
    - Travelers to foreign countries

Revaccinate two doses at 0 and ≥1 month

- Previously vaccinated with killed measles vaccine, or between 1963 and 1967 with an unknown measles vaccine

Revaccinate one dose

- Previously vaccinated with killed mumps vaccine, or before 1979 with an unknown mumps vaccine

*Evidence of immunity:

a. Documentation of MMR vaccination requires 2 doses for measles, 1 dose for rubella or mumps
b. Laboratory evidence of immunity
c. Documentation of physician diagnosis, or
d. Born before 1957 (age exceptions: rubella immunity not assumed for women of child-bearing age who could become pregnant; measles and mumps immunity possibly not assumed for health care workers).

Varicella Vaccine Series

Two doses at 0 and >4 weeks

- Healthcare workers without reliable histories of varicella or who have no serologic immunity
- Susceptible family and close contacts of immunocompromised persons
- Consider for susceptible persons who are at high risk for exposure (e.g., teachers of young children, college students, inmates and staff of correctional institutions, residents and staff of institutional settings, child care workers, military personnel, international travelers) and for women of childbearing age considering pregnancy. Avoid pregnancy for at least 4 weeks after vaccination.

Meningococcal Vaccine -- Use Meningococcal conjugate (Menactra) for adults <55 years and Meningococcal polysaccharide (Menomune) for those >55 years

Initial one dose

- College freshmen living in dormitories
- Persons who have functional or anatomic asplenia and terminal complement component deficiencies
- Travelers to sub-Saharan Africa from Senegal in the west to Ethiopia in the east, especially from December to June.
- Microbiologists routinely exposed to isolates of Neisseria meningitidis

Revaccinate: once every 3 to 5 years

- The above persons if indications still exist for vaccination and the last vaccination was given with Meningococcal polysaccharide.
- No need to revaccinate if previously vaccinated with Meningococcal conjugate (Menactra®)

Definitions:

Levels of Evidence

A. Randomized controlled trials
B. Controlled trials, no randomization
C. Observational trials

D. Opinion of expert panel

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Effective and timely administration of vaccines
- Decline in vaccine-preventable diseases

POTENTIAL HARMS

Rubella: No documented cases of congenital rubella syndrome have resulted from vaccination in early pregnancy, but this practice is not recommended.

CONTRAINDICATIONS

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- Influenza vaccine: patients with severe egg allergy should not receive the influenza vaccine.
- Measles, mumps and rubella (MMR) and varicella: pregnancy should be avoided for 4 weeks following immunization as this is a live vaccine.
- Measles, mumps and rubella (MMR): The combination vaccine should not be used for a patient who has a contraindication to an individual component.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These guidelines should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific clinical procedure or treatment must be made by the physician in light of the circumstances presented by the patient.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Foreign Language Translations
Patient Resources
Staff Training/Competency Material

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

University of Michigan Health System. Adult preventive health care: immunizations. Ann Arbor (MI): University of Michigan Health System; 2005 Nov. 11 p. [2 references]

ADAPTATION

The guideline was partially adapted from:

Recommended Adult Immunization Schedule by Vaccine and Age Group, United States, October 2005 - September 2006: Summary of Recommendations Published by the Advisory Committee on Immunization Practices. Atlanta, GA: Centers for Disease Control and Prevention, 2005. Available at: http://www.cdc.gov/nip/recs/adult-schedule-bw.pdf.

DATE RELEASED

2004 May (revised 2005 Nov)

GUIDELINE DEVELOPER(S)

University of Michigan Health System - Academic Institution

SOURCE(S) OF FUNDING

Internal funding for University of Michigan Health System (UMHS) guidelines is provided by the Office of Clinical Affairs. No external funds are used.

GUIDELINE COMMITTEE

Immunizations Guideline Team

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The University of Michigan Health System endorses the Guidelines of the Association of American Medical Colleges and the Standards of the Accreditation Council for Continuing Medical Education that the individuals who present educational activities disclose significant relationships with commercial companies whose products or services are discussed. Disclosure of a relationship is not intended to suggest bias in the information presented, but is made to provide readers with information that might be of potential importance to their evaluation of the information.

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GUIDELINE STATUS

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GUIDELINE AVAILABILITY

Electronic copies: Available for download in Portable Document Format (PDF) from the University of Michigan Health System Web site.

AVAILABILITY OF COMPANION DOCUMENTS

- Continuing Medical Education (CME) information is available from the University of Michigan Health System Web site.

PATIENT RESOURCES

The following are available:

- Adult immunization schedule. University of Michigan Health System; 2005 Sep. Various p. Available from the University of Michigan Health System Web site.
- Influenza vaccine. University of Michigan Health System; 2005 Sep. Various p. Available from the University of Michigan Health System Web site.
- Tetanus vaccine. University of Michigan Health System; 2005 Sep. Various p. Available from the University of Michigan Health System Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI on October 12, 2004. The information was verified by the guideline developer on October 22, 2004. This summary was updated by ECRI on October 5, 2005 following the U.S. Food and Drug Administration (FDA) advisory on Menactra (Meningococcal Conjugate Vaccine A,

C, Y, and W135). This NGC summary was updated by ECRI on February 23, 2006. The updated information was verified by the guideline developer on March 17, 2006.

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Date Modified: 9/25/2006